

Smiths Medical ASD Inc.
Critical Care Division
160 Weymouth Street
Rockland, MA 02370, USA
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www.smiths-medical.com

1083336

SECTION 5, 510(k) Summary**510(K) SUMMARY:****Company Information:**

Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370
(781) 878-8011, ext 7904
Contact: Ms. Christine Lloyd, Regulatory Affairs Specialist

JUN - 3 2009

Summary Prepared: May 1, 2009

Product Name:**Trade Name:**

- Level 1[®] Snuggle Warm[®] Adult Underbody Convective Warming Blanket (SW-2013)
- Level 1[®] Snuggle Warm[®] Left Lateral Access Convective Warming Blanket (SW-2014L)
- Level 1[®] Snuggle Warm[®] Right Lateral Access Convective Warming Blanket (SW-2014R)
- Level 1[®] Snuggle Warm[®] Upper Underbody Convective Warming Blanket (SW-2015)
- Level 1[®] Snuggle Warm[®] Full Body Split Access Convective Warming Blanket (SW-2016)
- Level 1[®] Snuggle Warm[®] Multi Access Convective Warming Blanket (SW-2018)
- Level 1[®] Snuggle Warm[®] Poncho Convective Warming Blanket (SW-2019)

Common Name: Convective Warming Blankets

Classification Name: Thermal Regulating System (21 CFR 870.5900, Product Code DWJ)

Predicate Device(s):

- K061513 Smiths Medical ASD, Inc., Level 1[®] Snuggle Warm[®] Pediatric Underbody Blanket and Level 1[®] Snuggle Warm[®] Large Pediatric Underbody Blanket (SW-2009 and SW-2011)
- K011907 Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Snuggle Warm[®] 4000 Convective Warming System. The Snuggle Warm[®] 4000 Convective Warming System consists of a Convective Warming Unit, a hose (that connects to the Convective Warming Unit on one end) and a blanket; which connects onto the other end of the hose. The forced warm air travels from the Warming Unit through the hose to the blanket that is placed on the patient. (SW-4000, EQ-5000, SW-2001, SW-2002, SW-2003, SW-2004, SW-2005, SW-2006, SW-2007, and SW-2010)

- K060865 Arizant Healthcare Inc., Bair Hugger® model 610 Full Body Surgical Blanket, model 555 Pediatric Underbody Blanket, model 550 Large Pediatric Underbody Blanket and model 545 Adult Underbody Blanket.

There are currently 10 variations of Convective Warming Blankets in the non-sterile convective warming blanket family.

Disposables Single-Use Blankets

- SW-2001 Full Body Convective Warming Blanket
- SW-2002 Pediatric Convective Warming Blanket
- SW-2003 Upper Body Convective Warming Blanket
- SW-2004 Lower Convective Warming Blanket
- SW-2005 Neonate to Small Child Intraoperative Convective Warming Blanket
- SW-2006 Premie to Neonate Intraoperative Convective Warming Blanket
- SW-2007 Tube Body Convective Warming Blanket
- SW-2009 Pediatric Underbody Convective Warming Blanket
- SW-2010 Large Upper Body Convective Warming Blanket
- SW-2011 Large Pediatric Convective Warming Underbody Blanket

Device Description:

Snuggle Warm® Convective Warming Systems (SW-4000 and EQ-5000) that will include the proposed blankets (Model SW-2013, SW-2014R, SW-2014L, SW-2015, SW-2016, SW-2018 & SW-2019)

- The Convective Warming Systems (SW-4000 and EQ-5000), are identified as a Thermal Regulation System by the FDA, consists of a Convective Warming Unit (temperature controller), a hose, and a single-use Convective Warming Blanket.
- The Convective Warming Systems' (SW-4000 and EQ-5000) single-use disposable Convective Warming Blankets are placed in contact with the patient and attached to a warming unit via a hose with hose-end temperature controls. The warming unit generates warm air that is distributed throughout the warming blanket to warm the patient during and after surgical procedures.
- It is intended for thermally regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures.

The seven proposed blankets are single-use Convective Warming Blankets that will be added to the existing Convective Warming Blanket family. They are components of the Convective Warming Systems (SW-4000 and EQ-5000) of which the indications for use remain the same.

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Technological Characteristics:

The proposed and predicate Snuggle Warm® convective warming blankets are made of similar materials and employ similar manufacturing processes. The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side of the blanket.

The proposed SW-2016 Full Body Split Access blanket, the SW-2018 Multi Access blanket and the SW-2019 Poncho blanket have movable panels which can be secured away from the surgical area similar to the Bair Hugger® model 610 Full Body Surgical Blanket.

Non-Clinical Data:

Bench testing was performed to demonstrate that the proposed convective warming blankets are substantially equivalent to the existing Snuggle Warm® convective warming blankets currently marketed by Smiths Medical. The blankets are designed to meet the requirements of the following standards:

- ASTM F2196:2002, Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management
- ISO 10993-1 2003, Biological Evaluation of Medical Devices – Evaluation and Testing

Clinical Data:

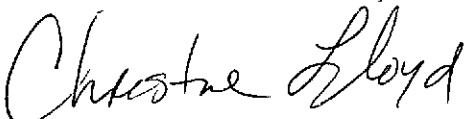
Not required

Conclusion:

The proposed Convective Warming Blankets are safe and effective as well being substantially equivalent to the predicate devices.

Very truly yours,

SMITHS MEDICAL ASD, INC.



Ms. Christine Lloyd
Regulatory Affairs Specialist



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2009

Smiths Medical ASD Inc.
c/o Ms. Christine Lloyd
Regulatory Affairs Specialist
Critical Care Division
160 Weymouth Street
Rockland, MA 02370

Re: K083336

Level 1® Snuggle Warm® Adult Underbody Convective Warming Blanket
(SW-2013)

Level 1® Snuggle Warm® Left Lateral Access Convective Warming Blanket
(SW-2014L)

Level 1® Snuggle Warm® Right Lateral Access Convective Warming Blanket
(SW-2014R)

Level 1® Snuggle Warm® Upper Underbody Convective Warming Blanket
(SW-2015)

Level 1® Snuggle Warm® Full Body Split Access Convective Warming Blanket
(SW-2016)

Level 1® Snuggle Warm® Multi Access Convective Warming Blanket
(SW-2018)

Level 1® Snuggle Warm® Poncho Convective Warming Blanket
(SW-2019)

Regulation Number: 21 CFR 870.5900

Regulation Name: Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass

Regulatory Class: Class II

Product Code: DWJ

Dated: May 1, 2009

Received: May 4, 2009

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate

commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

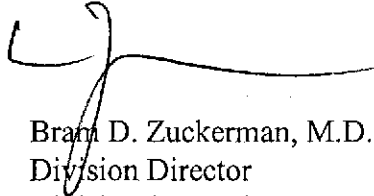
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free

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number (800) 638-2041 or (240) 276-3150 or at its Internet address
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Brad D. Zuckerman', with a long horizontal stroke extending to the right.

Brad D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: **Level 1® Snuggle Warm® Adult Underbody Convective Warming Blanket**

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number 6083336

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SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Level 1® Snuggle Warm® Left Lateral Access Convective Warming Blanket

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

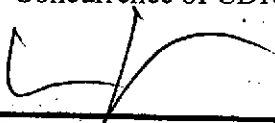
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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Division of Cardiovascular Devices
510(k) Number 1408 3336

Page 1 of 1

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Level 1® Snuggle Warm® Right Lateral Access Convective Warming Blanket

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

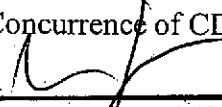
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083336

Page 1 of 1

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Level 1® Snuggle Warm® Upper Underbody Convective Warming Blanket

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Division of Cardiovascular Devices

510(k) Number 1083336

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SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: **Level 1® Snuggle Warm® Full Body Split Access Convective Warming Blanket**

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083336

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Level 1® Snuggle Warm® Multi Access Convective Warming Blanket

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083336

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SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Level 1® Snuggle Warm® Poncho Convective Warming Blanket

Indications for Use:

For thermal regulation of a patient's temperature to prevent hypothermia and/or reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Division of Cardiovascular Devices
510(k) Number 1083330

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